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Remarks

Claims 1-5 remain pending in the application.

Double Patenting

Claims 4-5 are rejected under the judicially created doctrine of obviousness-type double patenting. A terminal disclaimer complying with 37 CFR 1.321(c) is filed this response. Therefore, withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 U.S.C. § 103 (Lurie, Krikorian, & Ambrov)

Claims 2-5 are rejected under 35 U.S.C. § 103(a) as being obvious over Lurie et al., Cardiopulmonary Resuscitation and Assisted Circulation System, U.S. Patent 6,234,985 (May 22, 2001) in view of Krikorian, Coronary Augmenter, U.S. Patent No. 4,541,417 (Sep. 17, 1985) and Ambrov, Cardiac/Pulmonary Resuscitation Method and Apparatus, U.S. Patent No. 5,806,512 (Sep. 15, 1998) under the assertion that Lurie teaches the convention of using a mechanical compression means in combination with ventilation electrodes and a defibrillator, that it would have been obvious to modify Lurie to include counterpulsation electrodes as taught by Krikorian, and Ambrov teaches the convention of needing counterpulsation with CPR. Ambrov teaches away from the Applicant's claimed invention and the rejection further ignores the limitations of the Applicant's claims. Therefore, the Applicant respectfully traverses the rejection.

The Office action is confusing the term counterpulsion with the term counterpulsation. The terms are not interchangeable. Counterpulsation is a non-invasive treatment for cardiac disease that can reduce the symptoms of angina pectoris, presumably by increasing coronary blood flow in ischemic areas of the heart. Counterpulsation typically involves the use of a device to inflate

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and deflate a series of compressive cuffs wrapped around the patient's calves, lower thighs, and upper thighs. Inflation and deflation of the cuffs are modulated by events in the cardiac cycle via computer-interpreted ECG signals. During diastole, the cuffs inflate sequentially from the calves proximally, resulting in augmented diastolic central aortic pressure and increased coronary perfusion pressure. Compression of the vascular bed of the legs also increases venous return and cardiac output. Rapid and simultaneous decompression of the cuffs at the onset of systole permits systolic unloading and decreased cardiac workload. According to the American Heart Association, in the treatment regiments established to date, patients are treated with counterpulsation in 1 to 2 hour sessions over several weeks. The Applicant's claimed device uses a process called counterpulsion. Counterpulsion is a method in which slight pressure is applied to the abdomen in between each chest compression during CPR. (see specification page 5, lines 7-26).

The Applicant is claiming, *inter alia*, a controller for operating the chest compression device and the electro-stimulation system, said controller programmed to coordinate the operation of the chest compression device with the operation of the electro-stimulation system; wherein the controller operates the electrostimulation system to provide electrical signals to the ventilation electrodes and the counterpulsion electrodes when the chest compression device is decompressing the chest, and the controller operates the electrostimulation system to provide electrical signals to the defibrillation electrodes at or near the end of compressions caused by the chest compression device. There is no disclosure in Lurie, Krikorian, or Ambrov of the process of counterpulsion or a controller that is programmed to coordinate the operation of a chest compression device with the electrostimulation of ventilation electrodes, counterpulsion electrodes, and defibrillation electrodes.

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As the Examiner recognizes, Lurie fails to disclose a counterpulsation electrodes and must be combined with Krikorian. The rejection asserts Krikorian teaches the use of counterpulsation electrodes and the reference may be combined with Lurie resulting in the Applicant's claimed invention, but this is incorrect. The Applicant is simply not claiming counterpulsation. The Applicant claims counterpulsion. Counterpulsation is used on a living patient. The Applicant's device is not. As defined in the Applicant's specification, counterpulsion is a method in which slight pressure is applied to the abdomen in between chest compressions during CPR. The electrodes taught in Krikorian are stimulated by a triggering signal in response to a patient's heartbeat. (Col. 3, lines 8-23 and claim 1). Krikorian does not disclose a controller for coordinating a chest compression device and the electro-stimulation system wherein the controller operates the electrostimulation system to provide electrical signals to the ventilation electrodes, the counterpulsion electrodes and the defibrillation electrodes. The Applicant's system is used during CPR where the patient's heart has typically stopped. The Applicant's claimed invention does not produce a trigger signal in response to a patient's heartbeat because there is usually no heartbeat in the patient when CPR is being administered. Rather, the Applicant's claimed invention requires a controller wherein the controller operates the electrostimulation system to provide electrical signals to the ventilation electrodes and the counterpulsion electrodes when the chest compression device is decompressing the chest, and the controller operates the electrostimulation system to provide electrical signals to the defibrillation electrodes at or near the end of compressions caused by the chest compression device. The Krikorian system does not require this type of control system because it is for use on a living patient who does not require CPR. The combination of Lurie with Krikorian would simply be inoperable.

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The rejection further asserts Ambrov teaches the convention of needing counterpulsation with CPR, but the rejection is ignoring the Ambrov disclosure and further ignoring the limitations of the Applicant's claims. Ambrov is offered as an alternative to 'CPR using mechanical chest compressions. The test found in Graham v. John Deere requires a clear motivation to combine. Ambrov teaches a method and apparatus for resuscitating the cardiac/pulmonary activity of a patient with pneumatically controlled inflatable/deflatable cuffs secured over the patient's legs and abdomen and optionally the chest. The cuffs over the legs and abdomen enhance circulation of blood. (col. 4, lines 43-48). However, the the cuffs over the chest assists in breathing. (col. 4 lines 62-67, col. 5 lines 1-12). Ambrov explicitly teaches away from using mechanical pressure on a patient's chest for blood circulation as the Applicant claims. Specifically, Ambrov states the rate of blood flow achieved from mechanical compressions to the chest is low and the method carries a relatively high risk of bone and tissue damage. (col. 1, lines 9 - 20). One skilled in the art using mechanical chest compressions during CPR would not look to Ambrov. In addition, there is nothing in Ambrov that teaches use of an electrostimulation system during CPR to provide electrical signals to ventilation electrodes, and counterpulsion electrodes, and defibrillation electrodes. Ambrov does not use electrostimulation and there is no motivation found in Ambrov to modify its pneumatic system for use with an electrostimulation system during CPR.

Since Lurie and Krikorian individually or in combination fail to teach at least one limitation found in the Applicant's claimed invention, counterpulsion, the Applicant's claimed invention is not obvious. Further, there is no motivation found in Ambrov to use electrostimulation to facilitate counterpulsion during CPR or a motivation to use a pneumatic system found in Ambrov in combination with a mechanical chest compression system.

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Therefore, for at least these reasons withdrawal of this rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103 (Ambrov, Geddes & Krikorian)

Claims 4-5 are rejected under 35 U.S.C. § 103(a) as being obvious over Ambrov in view of Geddes, Demand electroventilator, U.S. Patent No. 4,827,935 (May 9, 1989) and Krikorian under the assertion that Ambrov teaches the combination of ventilation, chest compression and counterpulsion for CPR; that Geddes teaches an electrode ventilation system as an equivalent alternative to the ventilation system of Ambrov; and Krikorian teaches an equivalent alternative to the counterpulsion system of Ambrov. The rejection further states it would have been obvious to one of ordinary skill in the art to modify Ambrov to use the electro-stimulation system of Geddes as an obvious equivalent alternative means for providing ventilation and to use the electro-stimulation system of Krikorian as an obvious equivalent alternative counterpulsation system. The rejection ignores the limitations of the Applicant's claims and fails to show a motivation to combine the references. Therefore, the Applicant respectfully traverses the rejection.

The rejection is ignoring the limitations of the Applicant's claims. The Applicant claims, *inter alia*, an **electro-stimulation system** comprising a pair of ventilation electrodes, a pair of counterpulsion electrodes and an electrical generator, wherein the electrical generator generates a multiplicity of electrical signals and transmits the electrical signals to the pair of ventilation electrodes and a **controller** for operating the chest compression device and the **electro-stimulation system**, wherein the controller operates the electro-stimulation system when the chest compression device is decompressing the chest. Ambrov does not teach or disclose an **electro-stimulation system**, let alone a **controller** to control and coordinate a chest compression device with an **electro-stimulation system** comprising a pair of

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ventilation electrodes and a pair of counterpulsion electrodes. Geddes also fails to disclose a **controller** to control and coordinate a chest compression device with an **electro-stimulation system** comprising a pair of ventilation electrodes and a pair of counterpulsion electrodes. The Geddes apparatus requires monitoring the respiration of the patient for impedance changes and controlling the system in response to these impedance changes. The Geddes apparatus is used to assist a patient who already has some respiration occurring. As discussed *supra*, the Applicant's system is used during CPR, so respiration is not typically occurring in a patient at this time. Further, no chest compression device is disclosed or taught in Geddes. There is simply no controller to control and coordinate a chest compression device with an **electro-stimulation system** comprising a pair of ventilation electrodes and a pair of counterpulsion electrodes. Krikorian also fails to disclose the controller as previously discussed. Therefore, since Ambrov, Geddes, and Krikorian alone or in combination fail to disclose at least one limitation found in the Applicant's claimed invention, the Applicant's claimed invention is not obvious. Therefore, withdrawal of this application is respectfully requested.

The rejection also asserts Ambrov teaches the combination of ventilation, chest compression and counterpulsation for CPR, but the rejection is further ignoring the limitations of the Applicant's claims. The test for obvious found in Graham v. John Deere requires a clear motivation to combine. Ambrov teaches a method and apparatus for resuscitating the cardiac/pulmonary activity of a patient with pneumatically controlled inflatable/deflatable cuffs secured over the patient's legs and abdomen and optionally the chest. There is nothing in Ambrov that teaches counterpulsion, use of an electrostimulation system during CPR or use of chest compressions for blood circulation. Further, there is no suggestion found in Ambrov to use an electrostimulation system in place of the pneumatic system. The

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system taught in Ambrov only works with fluid filled bladders and there is no suggestion or motivation to replace the mechanical means taught in Ambrov with an electrostimulation system let alone a suggesting for a controller to control both a chest compression device and an electrostimulation system comprising a pair of ventilation electrodes and a pair of counterpulsion electrodes. Since Ambrov fails to teach a motivation to replace its pneumatically controlled system with an electrostimulation system the Applicant's claimed invention is not obvious. Therefore, withdrawal of this rejection is respectfully requested.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

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By:



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